UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PROCTER & GAMBLE COMPANY,	
	: Civil Action No. 07-8379 (RJS)
Plaintiff,	
v.	
	: DIRECT EXAMINATION
	: DECLARATION OF
ULTREO, INC.,	**: JAMES CHRISTOPHER McINNES**
Defendant.	

I, **JAMES CHRISTOPHER McINNES**, hereby declare under penalty of perjury as follows:

Background And Qualifications

1. I am the Principal Scientist at Ultreo, Inc. ("Ultreo") and am responsible for all clinical and laboratory research. I have held that position since 2004. I submit this Declaration in support of Ultreo's opposition to the motion for a preliminary injunction filed by The Procter & Gamble Company ("P&G") in this action, and in response to the October 10, 2007 Affidavit and November 27, 2007 Expert Report of Dr. Aaron Biesbrock, as well as the November 24, 2007 Expert Report of Robert J. Genco.

2. Prior to joining Ultreo in 2004, I was the Principal Scientist/Senior Research Scientist at Optiva Corporation. I subsequently became the Principal Scientist for Philips Oral Healthcare, Inc., the makers of the Sonicare® power toothbrush. I have over twenty years of experience in research and development ("R&D"), including coordinating and conducting clinical trials and laboratory studies in support of product claims and, along with several other colleagues, hold a number of patents relating to ultrasonic and other types or components of toothbrushes, as well as certain methods for quantitating the efficacy of oral care products.

3. I have written numerous journal articles, abstracts and invited articles on a variety of subjects in the field of oral health care, and have made presentations at a number of industry-related seminars and meetings.

4. I have a Bachelor of Science degree in mechanical engineering (BSME), and a Ph.D. degree in bioengineering. I received both of these degrees from the University of Washington, Seattle in 1986 and 1992, respectively.

5. A copy of my CV is annexed hereto as Exhibit A and can also be found at DX-51.[1]

The Development Of The Ultreo® Power Toothbrush

6. The Ultreo® power toothbrush is the result of a long and exhaustive R&D effort led by Dr. Pierre D. Mourad of the University of Washington ("UW") and of UW's Center for Industrial and Medical Ultrasound, in conjunction with a number of my colleagues at Ultreo. I was a member of the Ultreo team of engineers and scientists that took part in this project and have first-hand knowledge of Ultreo's efforts to develop the Ultreo® power toothbrush. In particular, I conducted a series of laboratory studies which sought to hone our knowledge of the various components of the Ultreo® and to help us to develop the product to the point where it was ready to be launched.

7. The objective of these studies was to determine the optimal ultrasound, sonic and microbubble parameters that would contribute to the overall efficacy of our product. To this end, my studies focused on issues relating to: (a) bubbles in dental fluid; (b) the determination of

[1] The exhibits that Ultreo intends to use at the preliminary injunction hearing have been pre-marked as Defendant's Exhibits ("DX-__").

the desired range of operating characteristics with respect to the Ultreo's® ultrasound parameters; and (c) the determination of the desired range of operating characteristics with respect to the Ultreo's® sonic parameters. I conducted these studies over the course of a three-year period (i.e., from 2004 through 2007), and investigated these issues in isolation and in combination. The research conducted over this three-year period, both at Ultreo and at the University of Washington, helped us to ascertain the desired operating characteristics that were ultimately employed within the Ultreo® power toothbrush. This research, along with the other studies conducted by Ultreo, convinced us that the Ultreo® was a safe and effective product that was ready to be launched into the market.

8. It is important to note that the Ultreo® was designed to be used in a fluid environment such that the sonic movement of the bristles not only physically dislodges dental plaque from the teeth, but also generates bubbles within the dental slurry (toothpaste, water, and saliva), surrounding the teeth during normal brushing. Bubbles within dental slurry have a distribution of sizes. REDACTED

(*See* DX-52 and DX-53). The Ultreo® was designed so that the ultrasound would activate some of these bubbles and cause them to pulsate in response to the ultrasound pressure waves.

The Proven Efficacy Of The Ultreo® Power Toothbrush As Demonstrated In Clinical Studies

9. Contrary to the assertions of Drs. Biesbrock and Genco (Biesbrock Expert Report ¶¶ 3-11; Genco Report ¶¶ 33-37), the efficacy of the Ultreo® has been unquestionably established in a clinical context. In a series of three *in vivo* clinical studies, the Ultreo® power toothbrush has been demonstrated to be safe and effective in reducing and removing plaque from

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all surfaces, including hard-to-reach interproximal areas, in reducing gingivitis, and in reducing extrinsic stains on teeth. These clinical studies, the details of which I will describe below, were conducted by Ultreo in conjunction with BioSci Research Canada Ltd. ("BioSci"), a leading independent clinical research facility that is used by P&G's Oral-B division, as well as other leading oral care companies.

10. In one clinical test, a total of 33 subjects participated in a study designed to evaluate the plaque removal efficacy of the Ultreo® power toothbrush after 1 and 2 minutes of brushing. The subjects were randomly assigned to one of two treatment arms: use of the Ultreo® for 1 minute, or use of the Ultreo® for 2 minutes. A product evaluation questionnaire was completed by the subjects at the conclusion of the study. The Ultreo®/BioSci study concluded that: (a) use of the Ultreo® for both 1 minute and 2 minutes resulted in a significant reduction in plaque; (b) the Ultreo® removed up to 95% of plaque from hard-to-reach interproximal areas during the first minute of brushing; (c) the Ultreo® was effective in removing plaque from all surfaces, including interproximal, gumline, and posterior regions; and (d) subjects using the Ultreo® experienced an immediate feeling of clean teeth after brushing. An abstract of this study can be found at DX-30.

11. In another clinical test involving 53 subjects, Ultreo and BioSci set out to evaluate the efficacy and the safety of the Ultreo® power toothbrush over a 30-day period in a population with mild to moderate gingivitis. The subjects were instructed to brush twice a day with their assigned toothbrush. Twenty-six subjects used the Ultreo® power toothbrush, and the remaining 27 subjects used the Oral-B® 35 manual toothbrush. A product evaluation questionnaire was filled out by the subjects at the end of the study. The results of this study demonstrated that: (a) the Ultreo® was shown to reduce gingivitis in 30 days; (b) the Ultreo® was significantly more

effective in reducing gingivitis than a manual toothbrush; (c) subjects using the Ultreo® perceived clean teeth and improved gingival health; and (d) both toothbrushes were found to be safe, as no adverse events were reported. An abstract of this study can be found at DX-31.

12. In yet another clinical study conducted with BioSci involving 22 subjects, the Ultreo® power toothbrush was shown to be safe and effective in reducing extrinsic stains on teeth. An abstract of this study can be found at DX-32.

The Proven Efficacy Of The Ultreo® Power Toothbrush As Demonstrated In Laboratory Studies

13. Laboratory studies are well-established and respected methodological tools used by members of the dental health research community in assessing both the safety and the effectiveness of oral hygiene products. I respectfully refer the Court to the Direct Examination Declaration of Dr. Joel Berg for an explanation of why this is the case. As described below, laboratory studies have unequivocally proven the efficacy of the Ultreo® power toothbrush.

The University Of Washington Study Of The Ultreo® Power Toothbrush

14. Ultreo, in conjunction with the University of Washington, has conducted laboratory research that has demonstrated that the Ultreo® power toothbrush's combined use of ultrasound waveguide technology and sonic bristle action can remove more plaque bacteria than either element used in isolation, and can remove plaque bacteria absent physical contact by the bristles. This research at the University of Washington led to a specific laboratory study in which the Ultreo® was compared to other power toothbrushes (the "UW Study"). An abstract of the UW Study can be found at DX-35.

15. The UW Study was designed based on published research by other power toothbrush manufacturers, notably Philips, in which a power toothbrush was studied for its ability to remove plaque bacteria *in vitro* without bristle contact. Ultreo sponsored the UW

Study under the direction of Dr. Frank Roberts of the UW School of Dentistry, Department of Periodontics. I assisted in the design and execution of this research using my knowledge gained in studying the Sonicare's ability to remove dental plaque bacteria *in vitro* without bristle contact. Dr. Roberts' laboratory personnel, Beth Hacker, Ph.D., an experienced research scientist, and Teresa Oswald, a microbiologist, handled the day-to-day activities associated with this research. Dr. Hacker and Ms. Oswald have no financial interest in or ownership ties to Ultreo.

16. In the UW Study, a biofilm of *Streptococcus mutans* ("*S. mutans*"), a particularly adhesive plaque bacteria, was grown on "hydroxyapatite" discs. Hydroxyapatite, also referred to as "hydroxylapatite," is a type of mineral, forms of which are found in dental enamel (the visible dental tissue of a tooth) and in dentin (the calcified tissue that lies beneath the dental enamel). The bacteria-coated discs were positioned three millimeters away from the bristle tips or ultrasound waveguide of: (a) an Ultreo® power toothbrush with the ultrasound device activated; (b) an Ultreo® power toothbrush with the ultrasound deactivated; (c) a Sonicare Elite® sonic power toothbrush; and (d) P&G's Oral-B Triumph® oscillating brush power toothbrush. The UW Study results showed that the ultrasound-activated Ultreo® power toothbrush removed significantly more plaque bacteria without bristle contact than the other three power toothbrush treatments.

17. In the same study, an *S. mutans* biofilm was grown on grooved glass slides. The surfaces of the slides were then brushed with the bristle tips of all four toothbrushes. Notably, the UW Study results showed that plaque bacteria within the grooves was observed to be substantially removed by the Ultreo® and removed to a lesser extent by other power toothbrushes. In sum, these test procedures plainly show that the Ultreo® toothbrush's ultrasound technology can remove plaque bacteria that toothbrush bristles cannot reach.

18. Claiming that a power toothbrush can remove plaque beyond the reach of its bristles is not unique to Ultreo. Philips, the current maker of Sonicare®, also claims in its advertising that its Sonicare® power toothbrush cleans beyond the reach of its bristles. Significantly, Sonicare® substantiates its beyond-the-bristles cleaning claim with laboratory – not clinical – studies. A copy of one of the many *in vitro* studies relied on by Philips can be found at DX-36.[2] Thus, P&G's assertion that the standard industry practice is that all toothbrush efficacy claims be substantiated with clinical research is untrue. Philips is the market leader with respect to premium power toothbrushes and is making beyond-the-bristles plaque removal claims while relying *solely* upon laboratory studies. Indeed, the UW Study is substantially similar to many of the Sonicare® studies and borrows upon published laboratory methods.

19. P&G itself has made beyond-the-bristles cleaning claims – based on the results of laboratory studies – as shown in, for example, an October 2004 compendium of studies produced by P&G in this action which is entitled "A Supplement To Compendium Of Continuing Education In Dentistry: Review Of Clinical Research On The IntelliClean System® From Sonicare® And Crest®." (DX-37; PG007055-104). The first page of the Compendium prominently states that it is "[s]upported by Philips Oral Healthcare, Inc. and The Procter & Gamble Company." (DX-37 at PG007055). Dr. Biesbrock has testified that P&G and Philips formed an alliance to jointly market the product, the IntelliClean System, that is the subject of this Compendium, and that both companies jointly sponsored and disseminated to the industry research in connection with that product:

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[2] Aspiras, M, Elliott, N, Nelson, R, et al. *In vitro* evaluation of interproximal biofilm removal with power toothbrushes. *Review of Key Clinical Research on the New Philips Sonicare FlexCare: A Supplement to Compendium of Continuing Education in Dentistry* 2007;28: 10-14 (DX-36).

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(Biesbrock Deposition of November 28, 2007, DX-144 at 76-77).

20. The IntelliClean System® was an integrated Sonicare® power toothbrush and Crest® liquid-toothpaste dispensing system that P&G had developed in conjunction with Philips. That product was jointly marketed and sold by P&G and Philips, but is no longer being offered by these two companies. One of the laboratory studies involving the IntelliClean System® which is contained in the Compendium is a study on which I am listed as a co-investigator. That study is entitled "*In vitro* Evaluation Of The Efficacy And Safety Of The IntelliClean System: Interproximal Biofilm Removal And Dentin Substrate Wear." (DX-37 at PG007098-104). Notably, the statements made in that joint Philips/P&G study squarely contradict the claims that P&G is making in this litigation. The study confirms that "*in vitro* test methods . . . provide objective analyses of the efficacy and safety of these oral hygiene products," and that they "provide methods of assessment of product efficacy representative of *what would be found in the oral cavity*," i.e., the mouth. (DX-37 at PG007104) (emphases added).

21. That study also found that the amount of plaque biofilm removed from hydroxyapatite disks by the IntelliClean System® absent physical bristle contact was significantly greater than that removed by an Oral-B® brand rotating/oscillating toothbrush. The Oral-B® brand toothbrush is, of course, the type of power toothbrush that P&G, as a result of acquiring Gillette and its Oral-B® brand in 2005, currently manufactures. The study concluded that:

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> The IntelliClean System® toothbrush, with its associated dynamic fluid activity, demonstrates superior removal of biofilm as compared to a power toothbrush with conventional rotating/oscillating bristle motion . . . . [and that] [t]he results presented here validate that the IntelliClean System® is both safe and efficacious and provide the consumer and dental professional with information allowing an informed choice in oral hygiene product selection.

(DX-37 at PG007104).

22. Other articles in the Compendium confirm that P&G has extolled the virtues of beyond-the-bristles cleaning claims based on laboratory studies. For instance, the lead article in the Compendium, which is co-authored by a P&G Senior Scientist and which is entitled "A Novel Oral Hygiene System Through Integration Of A Sonic Toothbrush And Liquid Toothpaste" (DX-37 at PG007058-61), explains that central to the Sonicare® toothbrush within the IntelliClean System® is its "side-to-side motion of the bristle tips[], which creates dynamic fluid activity in the mouth," and that "[a]ccording to *in vitro* studies conducted by Hope and Wilson[] and Adams and colleagues[], such fluid activity can remove plaque from beyond the reach of the bristles significantly better than a rotational-oscillation power toothbrush." (DX-37 at PG007059). That same article states that, like other Sonicare® toothbrushes, the IntelliClean System® "has also been shown *in vitro* by Yuen and coworkers[] to exhibit 'beyond-the-bristles' cleaning and to be gentle on dentin, significantly more so than the Oral-B® ProfessionalCare7000, a leading rotational oscillation toothbrush." (DX-37 at PG007061).[3]

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[3] Collectively citing Hope, CK, Wilson, M. Comparison of the interproximal plaque removal efficacy of two powered toothbrushes using *in vitro* oral biofilms. *Am. J. Dent.* 2002; 15 (spec no): 7B-11B (DX-41); Adams, H, Winston, WT, Heersink, J, et al. Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing. *Am. J. Dent.* 2002;15 (spec. no.): 12B-17B (DX-38); Yuen, AF, Nelson, R, Johnson, MR, et al. *In vitro* evaluation of the efficacy and safety of the IntelliClean System: interproximal biofilm removal and dentin substrate wear. *Compend. Contin. Educ. Dent.* 2004;25 (suppl. 1):44-50 (DX-39).

Significantly, nowhere in that article do the authors state that the results of laboratory or *in vitro* studies upon which they have relied must be corroborated by clinical studies.

23. Also within that Compendium is an article regarding a clinical gingivitis study co-authored, in part, by Ashley P. Barlow, a P&G Senior Scientist, and Xiaojie Zhou, a P&G Senior Statistician, and entitled "Effect Of A Novel Integrated Power Toothbrush And Toothpaste Oral Hygiene System On Gingivitis." (DX-37 at PG007069-74). The authors note that: "[u]nlike many power toothbrushes, the Sonicare® toothbrush was designed to deliver not only physical bristle contact with the teeth to remove plaque[,] but also a fluid dynamic action derived from the bristle motion that has been shown *in vitro* to disrupt plaque biofilms." (DX-37 at PG007070).[4]

24. In another article regarding a clinical study, entitled "Plaque Reduction Over Time Of An Integrated Oral Hygiene System" (DX-37 at PG007062-68), the co-authors echo this sentiment about *in vitro* studies, stating that "[i]n certain power toothbrushes, notably the Sonicare® toothbrush, the brush's high frequency motion not only cleans by direct bristle-tooth contact[,] but also creates dynamic fluid pressure and shear forces that have been shown in laboratory studies to disrupt and disperse bacterial plaque beyond the reach of the bristles." (DX-37 at PG007062).[5]

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[4] Citing Adams, H, Winston, WT, Heersink, J, et al. Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing. *Am. J. Dent.* 2002;15 (spec. no.): 12B-17B (DX-38); Hope, CK, Petrie, A, Wilson, M. *In vitro* assessment of the plaque-removing ability of hydrodynamic shear forces produced beyond the bristles by 2 electric toothbrushes. *J. Periodontol.* 2003;74:1017-22 (DX-40).

[5] Citing Hope, CK, Wilson, M. Comparison of the interproximal plaque removal efficacy of two powered toothbrushes using *in vitro* oral biofilms. *Am. J. Dent.* 2002; 15 (spec no): 7B-11B (DX-41); Hope, CK, Petrie, A, Wilson, M. *In vitro* assessment of the plaque-removing ability of hydrodynamic shear forces produced beyond the bristles by 2 electric toothbrushes. *J. Periodontol.* 2003;74:1017-22 (DX-40); Adams, H, Winston, WT, Heersink, J, et al. Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing. *Am. J. Dent.* 2002;15 (spec. no.): 12B-17B (DX-38).

25. Moreover, another article written by P&G scientists in the Compendium is entitled "Pharmacodynamic And Pharmacokinetic Effects In Gingival Crevicular Fluid From Re-dosing During Brushing." (DX-37 at PG007075-81). I note that one of the authors, Dr. Tao He of P&G, is also a co-author of the P&G Clinical Study, discussed below, which P&G has offered in connection with this action in order to evaluate the effectiveness of the Ultreo®.

26. As Dr. Biesbrock has testified,

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(Biesbrock Dep., DX-144 at 79, 99-100).

27. In this Compendium article, Dr. He and her co-authors refer to the "proven hydrodynamic action of sonic brush technology" (DX-37 at PG007076), and cite to support that statement an *in vitro* study that examined the plaque-removing ability of hydrodynamic shear forces to clean beyond-the-bristles. (DX-37 at PG007081).[6] The word "proven" is not one that is used lightly by scientists and at no point in the article do Dr. He and her co-authors state that such proof can only be obtained though clinical studies.

28. P&G has, in short, made beyond-the-bristles claims for its own integrated oral care products. As noted above, those claims have been made on the basis of laboratory studies which, by P&G's own admission, demonstrate the safety of such products and the efficacy of their beyond-the-bristles cleaning capabilities. As Dr. Biesbrock has testified,

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[6] Citing Hope, CK, Petrie, A, Wilson, M. *In vitro* assessment of the plaque-removing ability of hydrodynamic shear forces produced beyond the bristles by 2 electric toothbrushes. *J. Periodontol.* 2003;74:1017-22 (DX-40).

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(Biesbrock Dep., DX-144 at 89). Hence, P&G can hardly contest the fact that claims based on the results of laboratory tests using scientifically reliable methods are perfectly acceptable within the oral healthcare industry.

Other Laboratory Studies Have Proven The Safety Of The Ultreo®

29. A laboratory study conducted at the Pacific Dental Institute in Portland, Oregon set out to compare the Ultreo® toothbrush to two controls (a manual toothbrush and a power toothbrush) after a simulated 1-year brushing period with respect to wear on natural tooth surfaces, cements and restorative materials. The results of this study have shown that the Ultreo® power toothbrush is gentle on natural tooth surfaces and restorative materials. Similarly, a laboratory study conducted at the same Institute set out to compare the Ultreo® toothbrush to two controls (a manual toothbrush and a power toothbrush) after a simulated 2 year brushing period with respect to retention force of orthodontic brackets and crowns. This study found that none of the treatments significantly affected the retention force of orthodontic brackets and crowns. Abstracts of these studies can be found at Exhibits DX-45 and DX-46.

30. Moreover, a separate *in vitro* study conducted at the University of Washington set out to evaluate the safety of the Ultreo® power toothbrush's sonic and ultrasound processes using *in vitro* models of soft tissue. The study found that the Ultreo® power toothbrush does not harm soft tissue cells. An abstract of this study can be found at DX-47.

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The Affidavit and Expert Report Of Dr. Aaron Biesbrock
And The Expert Report of Dr. Robert J. Genco

31. I have read the affidavit and/or the expert reports that Dr. Biesbrock and Dr. Genco have submitted in support of P&G's request for a preliminary injunction. Their criticisms of *in vitro* studies and of Ultreo's UW Study are wholly without merit for a number of reasons.

32. I have reviewed certain documents produced to Ultreo by P&G (DX-48 at PG000672-81) that unequivocally show that P&G's own laboratory studies, which have replicated the methodologies that were used in Ultreo's UW Study, demonstrate that the ultrasound-activated Ultreo® removed significant quantities of plaque bacteria without bristle contact.

33. In a series of laboratory studies, P&G compared the Ultreo® with and without its ultrasound activated, to the Sonicare® Elite power toothbrush and the Oral-B® power toothbrush, using hydroxyapatite discs and plaque biofilm.

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(DX-48 at PG000676 and PG000679).

34. Notably, during the course of his deposition, Dr. Biesbrock confirmed that P&G's laboratory tests replicated the results that Ultreo had attained during the course of the UW Study:

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(Biesbrock Dep., DX-144 at 131). Indeed, Dr. Biesbrock testified that

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(Biesbrock Dep., DX-144 at 138).

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35. Dr. Biesbrock's and Dr. Genco's criticisms of *in vitro* studies in general are also misguided. Their contention that the type of bacteria that is used in *in vitro* studies does not mimic the plaque bacteria that is found in the human mouth is wrong. (Biesbrock Aff. at ¶ 14; Genco Report at ¶¶ 12-17). Indeed, they note, in a rather hyperbolic fashion, that 30 to 500 types of plaque bacteria exist. (Biesbrock Aff. at ¶ 14; Genco Report at ¶ 15).

36. One of those strains or types of bacteria, however, is *S. mutans* – the bacteria used in the above-mentioned UW Study of the Ultreo® power toothbrush. It is well-established that *S. mutans* is commonly found in the human mouth. It is especially suited for use in dental research studies precisely because the tenacious nature of its growth in the laboratory is a model for the properties of naturally-forming plaque bacteria in the human mouth.

37. Moreover, it is also widely-recognized within the dental profession that *S. mutans* is a particularly harmful strain of bacteria. This type of bacteria is a leading cause in the formation of dental "caries," a type of disease that affects the structure of human teeth. When left untreated, dental caries lead to the formation of what the lay public commonly recognizes as "tooth decay" and "cavities."

38. Dr. Biesbrock's claim that "[t]he presence of salivary protein in the mouth may also impact the effectiveness of plaque-removal efforts" (Biesbrock Aff. at ¶ 16), and that this fact compromises the validity of *in vitro* study results, is similarly misplaced. As noted above, in the UW Study, a biofilm of *S. mutans* was grown on hydroxyapatite discs. The surface of the hydroxyapatite discs was coated with gastric mucin. Gastric mucin is a well-recognized substitute for naturally-occurring human saliva in laboratory studies and is routinely used by

dental researchers. Indeed, Philips also uses gastric mucin in its *in vitro* studies.[7] Accordingly, the methodology employed in the UW Study takes into account the impact that the presence of salivary proteins may have on plaque removal efforts.

39. Dr. Biesbrock's all-encompassing statement that *in vitro* studies are not accurate predictors of *in vivo* plaque removal efforts because "most of these *in vitro* studies are conducted with the toothbrush head fully submerged in water (or a similar liquid)," and because "an individual's mouth is never completely filled with saliva" (Biesbrock Aff. at ¶ 17), is also incorrect.

40. During the course of the UW Study, the Ultreo® power toothbrush head was *not* fully submerged in water or any other fluid. Indeed, just a portion of the Ultreo® toothbrush head's bristles was immersed in fluid. This partial-submersion protocol was used because the presence of air is integral to the formation of bubbles, which is an important factor with respect to the plaque removal capabilities of the Ultreo® toothbrush. Not surprisingly, Philips also uses a partial-submersion protocol in its "beyond-the-bristles" *S. mutans* laboratory studies.[8]

41. Furthermore, Dr. Biesbrock's intimation that *in vitro* studies using a full-submersion testing protocol are deficient because the volume of saliva found in the human mouth at any given time is "1.07 milliliters, plus or minus 0.39 milliliters" (Biesbrock Aff. at ¶ 17) is

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[7] *See* Hope, CK, Wilson, M. Comparison of the interproximal plaque removal efficacy of two powered toothbrushes using *in vitro* oral biofilms. *Am. J. Dent.* 2002; 15 (spec no): 7B-11B (DX-41); Hope, CK, Petrie, A, Wilson, M. *In vitro* assessment of the plaque-removing ability of hydrodynamic shear forces produced beyond the bristles by 2 electric toothbrushes. *J. Periodontol.* 2003;74:1017-22 (DX-40).

[8] *See* Adams, H, Winston, WT, Heersink, J, et al. Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing. *Am. J. Dent.* 2002;15 (spec. no.): 12B-17B (DX-38); Wu-Yuan, C, McInnes, C. Ability of the Sonicare® electronic toothbrush to generate dynamic fluid activity that removes bacteria. *J. Clin. Dent.* 1994;5 89-93 (DX-43).

quite misleading and, as explained below, simply inapplicable to the actual protocol employed in the UW Study of the Ultreo® toothbrush.

42. Dr. Biesbrock fails to note that 1.07 milliliters of saliva may be found in the human mouth when the mouth is in a *passive* or *resting* state. By way of example, one's mouth is in a passive or resting state when one is not eating. Studies show that when stimulated, for example, by chewing or brushing, saliva is generated at a rate greater than 2 milliliters per minute.[9] Thus, during a typical two-minute brushing, an additional 4 milliliters of fluid (saliva) may be generated in addition to resting saliva. Moreover, additional fluid is introduced into the mouth in the form of water that one puts on a toothbrush before beginning to brush. Since saliva is being generated during brushing, the amount of fluid in the mouth varies during a brushing episode, but, all told, there are approximately 2 to 6 milliliters of fluid in the mouth, rather than the 1.07 milliliters cited by Dr. Biesbrock. Indeed, in an *in vivo* test conducted early in Ultreo's® development, I set out to measure the amount of fluid customarily found in the human mouth during typical brushing with a power toothbrush. Based on expectorated fluid from 7 volunteers, I found that the amount of fluid in the mouth after 60 seconds of brushing ranged from approximately 1.5 to 6.8 milliliters, for an average of 4.5 milliliters.

43. Furthermore, P&G's contention that the surface that is intended to represent teeth in certain *in vitro* studies is often not an acceptable substitute (Biesbrock Aff. at ¶ 17; Genco Report at ¶¶ 16, 39), is inapplicable to the UW Study of the Ultreo® toothbrush. As noted above, hydroxyapatite discs contain the mineral found in dental enamel and in dentin and are commonly used within the scientific community as an appropriate substitute for teeth. Indeed,

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[9] *See* Bergdahl, M. Salivary flow and oral complaints in adult dental patients. *Community Dent Oral Epidemiol* 2000;28: 59-66 (DX-44).

Philips has been using them for years in their clinical studies involving the Sonicare®.

44. P&G's own documents confirm the appropriateness of using hydroxyapatite discs. P&G has produced documents that admit, in connection with the above-mentioned P&G laboratory studies that replicate Ultreo's UW Study, as follows:

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(*See* DX-49 at PG000248). Indeed, Dr. Biesbrock testified that this was the objective of the study's design:

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(Biesbrock Dep., DX-144 at 126).

45. Moreover, in the UW Study, a biofilm of *S. mutans* was also grown on grooved glass slides, the surfaces of which were brushed with bristle tips of all four toothbrushes. The results showed that plaque bacteria within the grooves was observed to be substantially removed by the Ultreo® and removed to a lesser extent by other power toothbrushes. Significantly, Philips has also used glass slides, in addition to hydroxyapatite disks, in laboratory testing of its Sonicare® line of power toothbrushes.[10]

[10] Adams, H, Winston, WT, Heersink, J, et al. Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing. *Am. J. Dent.* 2002;15 (spec. no.): 12B-17B (DX-38).

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46. Dr. Biesbrock's contention that "some *in vitro* studies fail to use toothpaste, which can have an impact on both bacteria and plaque" (Biesbrock Aff. at ¶ 17), also has no application to the UW Study. The UW Study of the Ultreo® power toothbrush *did* use toothpaste.

47. Finally, Dr. Genco gratuitously opines that it is unlikely that he would have published the UW Study in any of the journals – i.e., the *Journal of Periodontology* and the *Annals of Periodontology* – for which he was the Editor from 1988 until 2006, absent clinical data confirming the results of that *in vitro* study. (Genco Report at ¶ 38). However, it is instructive to note that Dr. Genco has, in fact, published an *in vitro* study which, by P&G's own admission in the IntelliClean® System Compendium discussed above, supports the beyond-the-bristles cleaning claims P&G has made in the past. *See* Hope, CK, Petrie, A, Wilson, M. *In vitro* assessment of the plaque-removing ability of hydrodynamic shear forces produced beyond the bristles by 2 electric toothbrushes. *J. Periodontal.* 2003;74:1017-22. (DX-40). Neither the Hope, Petrie & Wilson study published in the *Journal of Periodontology*, nor any of the articles or studies contained in the IntelliClean® System Compendium sponsored by and disseminated to the professional dental community by P&G, state that the results of laboratory or *in vitro* studies must be corroborated by clinical studies

P&G's Clinical Study Is Deficient In Several Major Respects

48. I have reviewed P&G's clinical study, entitled "A Clinical Study Evaluating the Effects of a Sonic Toothbrush with Ultrasound Waveguide in Disrupting Plaque with and without Bristle Contact" (the "P&G Clinical Study"). That study, which appears to have been conducted internally at P&G, is authored by four P&G employees. I believe the test is seriously flawed in a number of respects. It employs a number of unproven and methodologically suspect protocols and, it appears, was specifically designed to achieve the results that P&G desired.

49. The P&G Clinical Study fails to demonstrate anything about the contribution of *ultrasound* to the Ultreo® power toothbrush's plaque removal capabilities. The study did not, as one might expect, compare the Ultreo® toothbrush with its *ultrasound* component *activated*, to the Ultreo® with its ultrasound component *deactivated.* Instead, the study compared the Ultreo® toothbrush turned on (thus activating both the sonic and ultrasound processes), with the Ultreo® toothbrush turned off (thus deactivating both the sonic and ultrasound processes) and used as a manual toothbrush. The contribution of ultrasound was not isolated.

50. The novelty of this unorthodox protocol cannot be underestimated. Indeed, when asked during the course of his deposition whether P&G had ever conducted a clinical study involving the use of a power toothbrush in an inactive mode (i.e., used as a manual toothbrush), Dr. Biesbrock's response was unequivocal – and telling: REDACTED

(Biesbrock Dep., DX-144 at 150) (italics added).

51. The study also purports to mirror the UW Study by directing that the Ultreo® power toothbrush brushhead be held by a dental hygienist at a three millimeter distance from the tooth surface of the subject. A copy of the brushing instructions used by the hygienists in the P&G Clinical Study can be found at DX-50 (PG001486). REDACTED

The ultrasound delivered out of the tip of the waveguide is likely close to only a single tooth surface. By not moving the brush in the mouth, the waveguide tip never came close to the majority of the teeth.

52. Moreover, one of, if not *the* most, critical problem with P&G's approach in an *in vivo* context, is that with the mouth open for the hygienist to perform the brushing, there will not be sufficient fluid near the ultrasound waveguide tip of the toothbrush to allow the ultrasound to

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work. It is impossible for a patient to keep his or her mouth open so as to permit a hygienist to observe the activity and still maintain a realistic fluid environment typical of normal brushing. This means that the ultrasound will not be able to activate microbubbles so that they can pulsate and help clean teeth.

53. Dr. Biesbrock admitted that P&G's attempt to replicate Ultreo's laboratory study in a clinical context is fraught with problems in this regard. When asked how P&G made sure that the fluid was sufficiently around the waveguide so that it caused the coupling necessary for the Ultreo® to work effectively, Dr. Biesbrock opined that this was

REDACTED (Biesbrock Dep., DX-144 at 191).

54. Documents produced by P&G also demonstrate that P&G employees were used as subjects in this study.

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REDACTED

55. Moreover, while Dr. Genco underscores the fact that the plaque examiner in the P&G study was blinded (Genco Report at ¶ 25), this does not obviate the fact that the actual participants in the study were not. As Dr. Biesbrock explained in his deposition:

REDACTED

(Biesbrock Dep., DX-144 at 156-57).

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[11] Dr. Genco notes that P&G's clinical study has been accepted for publication in *The American Journal of Dentistry* and that "[t]his acceptance demonstrates that the study met the criteria for design, implementation and analysis of a widely-accepted scientific journal." (Genco Report at ¶ 32). It is instructive to note, however, that that same journal has also published some of the very same laboratory studies upon which P&G has relied in the past for its beyond-the-bristles cleaning claims. *See* Hope, CK, Wilson, M. Comparison of the interproximal plaque removal efficacy of two powered toothbrushes using *in vitro* oral biofilms. *Am. J. Dent.* 2002; 15 (spec no): 7B-11B (DX-41); Adams, H, Winston, WT, Heersink, J, et al. Development of a laboratory model to assess the removal of biofilm from interproximal spaces by powered tooth brushing. *Am. J. Dent.* 2002;15 (spec. no.): 12B-17B (DX-38).

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56. In a study involving a competitor's toothbrush, where subject behavior can influence the outcome, the use of employees cannot, under any stretch of the imagination, be considered unbiased. Yet, it appears that P&G has sacrificed these principles at the altar of cost and expediency.

57. The P&G Clinical Study also purports to show that the Ultreo® power toothbrush performs better when used as a manual toothbrush, rather than as a power toothbrush. This result is inconsistent with Ultreo's own clinical research, which shows that the Ultreo® power toothbrush outperforms a manual brush in both overall and interproximal plaque reduction. The result is also inconsistent with Oral-B's own clinical research, which indicates that its power toothbrushes consistently outperform manual toothbrushes. Philips' research similarly shows that its power toothbrush will outperform a manual toothbrush. In light of all this research, it has become accepted in the dental research community that a power toothbrush is superior to a manual toothbrush.[12]

58. P&G's attempt to replicate Ultreo's laboratory UW Study in a clinical setting is fraught with a number of major deficiencies. I believe that P&G has employed a number of bizarre and unprecedented protocols in a clinical context in order to achieve the litigation results it desired.

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[12] I am not currently aware of any P&G documents that shed light on the type of instructions P&G issued to subjects with respect to the use of the Ultreo® as a manual toothbrush. The lack of any written instructions would, of course, raise yet another serious issue about the methodology employed by P&G during the course of this study.

P&G's Reliance On The Philips *In vivo* Study Of The Ultreo® Is Misplaced

59. Dr. Biesbrock claims that Philips' *in vivo* study that purports to measure the plaque removal capabilities of the Sonicare FlexCare® and the Ultreo® (with its ultrasound function activated and disabled) is relevant is assessing the overall efficacy of the Ultreo®. (Biesbrock Aff. at ¶ 36 and Exhibit S). I disagree. The only information upon which Dr. Biesbrock bases his claim about the Philips study is an abstract published by Philips. His deposition testimony with respect to this point makes this fact plain:

REDACTED

(Biesbrock Dep., DX-144 at 207). Indeed, Dr. Genco concedes that P&G's knowledge about the Philips study is "only presented in abstract form and cannot be critically evaluated for methodology." (Genco Report at ¶ 32). Thus, P&G is simply not in any position to opine on the validity of Philips' purported results since the parties do not have the underlying data that support this study.

60. Moreover, it is instructive to note that in the course of this study Philips "disabled" the ultrasound function of the Ultreo® power toothbrush. In other words, it appears that Philips dismantled the Ultreo® power toothbrush. Given the lack of information that Ultreo has about the Philips study, we are unable to assess whether Philips' actions in taking the Ultreo® apart have had an adverse impact upon the capabilities of the Ultreo®, or have in some

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manner artificially enhanced the power of the Ultreo's® sonic bristle motion when the ultrasound was disabled.

61. Finally, and for the reasons explained by Dr. Berg in his Direct Examination Declaration, it is generally recognized that traditional, visible examination techniques utilized by researchers during the course of clinical research studies are fraught with a number of limitations. These indices are highly subjective and are not sensitive enough to record all differences in plaque removal.

62. For example, the Turesky Plaque Index (a grading of plaque with scores from 0 to 5) used by P&G in its study, assigns a score of 5 to any plaque that covers more than two-thirds of the tooth surface. A tooth that is fully covered with plaque before brushing (a Turesky score of 5) and only two-thirds covered with plaque after brushing (a Turesky score of 5) is therefore scored by this subjective index as having no plaque removal (5 before minus 5 afterwards results in 0 removal). Thus a full one-third of plaque may be removed from the tooth surface but be scored as having no plaque removal. Furthermore, since the Turesky Index considers only the area covered with plaque, and not thickness, the plaque may be substantially thinned but not totally removed. Thus, subjects will experience a feeling of clean as a result of the thinning of plaque, but this difference will not be reflected in any plaque score recorded pursuant to this index.

63. Also, since plaque index scores rely on examination of the tooth surface by normal visual acuity, removal of plaque from regions smaller than those that can be seen by the human eye is not detected. Individual plaque bacteria are on the order of 1 micrometer – too small to be seen without magnification. Hundreds of thousands of bacteria may fit on a rounded

dot made by a pencil.[13] Scaled accordingly, hundreds of millions of bacteria may be covering an individual tooth that has been scored a 5 on the Turesky scale. The fact that one-third of the plaque bacteria can be removed with no change in plaque score means that hundreds of millions of bacteria can be removed, but not detected via these visual indices. These visual plaque indices have utility in assessing the overall general oral health status of subjects, but were never designed with enough sensitivity to assess fine differences in plaque removal.

64. Furthermore, since mechanical brushing by subjects removes so much of the visible plaque on teeth, it is difficult to evaluate through visual examination whether there are any additional benefits achieved from other technological components of power toothbrushes, such as those contained in the Ultreo® power toothbrush.

The Opinions Expressed In Dr. Biesbrock's Expert Report Are Misguided

65. Dr. Biesbrock and Dr. Genco also take issue with a separate in-house clinical study conducted here at Ultreo, which I co-authored with two colleagues. In this study, 14 subjects participated in a 4 week pilot study. Subjects reported for all study visits with 12-18 hours of plaque and brushed during each evaluation. They were assigned at random to an oral hygiene regimen, using either the Ultreo® power toothbrush without the use of dental floss, or a manual toothbrush with the use of dental floss. At the baseline visit prior to each treatment period, visible plaque was removed. The subjects were asked to brush twice a day and, for the manual group, to floss once per day. The subjects continued with each oral hygiene regimen for a 2 week test period, after which they crossed over to the other regimen for a 2 week test period. The results of this clinical study showed that the Ultreo® was effective in removing overall and

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[13] *See Bacteria.* MSN Encarta: http://encarta.msn.com/text_761574409___0/Bacteria.html (November 27, 2007) (DX-42).

hard-to-reach plaque. Although there was not a statistical difference between treatments when considering both visits together, there was when considering plaque formed after the first week of brushing. For the manual toothbrush and floss there was a significant ($p<0.01$) increase in overall and interproximal plaque from the first to second week. In contrast there was no significant increase in either overall or interproximal plaque for the Ultreo®. The results indicate that, over time, the use of the Ultreo® resulted in less plaque forming on the tooth surface. Notably, while P&G expends a lot of energy criticizing this study, it is instructive to note that Ultreo has not made product claims on the basis of the results obtained in this pilot study.

The Ultreo® Toothbrush Generates Approximately 4 Million Cycles of Ultrasound Energy

66. I have calculated the number of cycles of ultrasound energy generated by the Ultreo® power toothbrush. A copy of the documented results of my calculation can be found at DX-34. The Ultreo® power toothbrush generates approximately four million cycles of ultrasound energy per two-minute brushing.

Conclusion

67. Ultreo has conducted sufficiently reliable laboratory and clinical tests that demonstrate, with reasonable certainty, the efficacy and safety of its toothbrush, and has faithfully reported the results of its research. I believe that the UW Study conducted by Ultreo demonstrates that the Ultreo's® combined use of ultrasound technology and sonic bristle action is effective in removing plaque bacteria from model dental surfaces without physical contact by the bristles.

Dated: December 11, 2007
Redmond, Washington

James Christopher McInnes

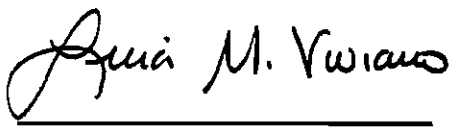
CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on December 12, 2007, I caused a copy of the foregoing **REDACTED DIRECT EXAMINATION DECLARATION OF JAMES CHRISTOPHER MCINNES** to be served upon counsel for The Procter & Gamble Company by the Court's ECF Filing System and by hand delivery to the following individual:

Laura W. Sawyer
JONES DAY
222 East 41st Street
New York, New York 10017

Attorneys for The Procter & Gamble Company

Dated: New York, New York
December 12, 2007



Lina M. Viviano